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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,470	10/16/2003	Warren Stern	SOHN-P01-001	8880
28120	7590	01/14/2008		
ROPES & GRAY LLP PATENT DOCKETING 39/41 ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER SCHLIENTZ, NATHAN W	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			01/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/687,470

**Applicant(s)**

STERN, WARREN

**Examiner**

Nathan W. Schlientz

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,8,9 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/20/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Status of Claims*

Claims 1 and 5-11 are pending with claims 7 and 10 being withdrawn. Claims 1 and 11 are amended in an amendment filed 20 August 2007. Therefore, claims 1, 5, 6, 8, 9 and 11 are examined herein on the merits for patentability. No claim is allowed at this time.

### *Withdrawn Rejections*

1. The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby **withdrawn** by the examiner in light of the claim amendment listing formulas I-XVIII in the claims.
2. The rejection of claims 1, 5, 6, 8, 9 and 11 under 35 U.S.C. 103(a) as being unpatentable over WO 03/053221 (Ieni) in view of either Senior et al. or Xiao et al. is hereby **withdrawn** by the examiner in light of the evidence by Applicants that obstructive sleep apnea syndrome (OSAS) and partial nocturnal upper airway obstruction are clinically distinct conditions.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5, 6, 8, 9 and 11 stand rejected under 35 U.S.C. 102(e) as being anticipated by WO 03/097011 A1 (Barth et al.).

The instant claims are drawn to a method for reducing ***partial nocturnal upper airway*** obstruction comprising administering lansoprazole. Barth et al. disclose a method of treating OSAS or obstructive sleep apnea (OSA), which is caused by a complete and/or ***partial obstruction of the patient's airway*** (a.k.a. obstructive hypopnea) (page 8, lines 9-14) by administering a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H<sup>+</sup>, K<sup>+</sup>-ATPase), such as lansoprazole (a.k.a., Prevacid) (page 13, lines 20-21; page 19, lines 8-16; page 27, lines 32-35; page 28, lines 4-7).

***Response to Arguments***

Applicant's arguments filed 20 August 2007 have been fully considered but they are not persuasive. Applicants argue on pages 13-16 that OSAS and primary snoring are two distinct disease conditions that may require different treatments. Also, applicants argue that snoring may be a symptom in some but not all OSAS patients.

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Applicants direct attention to the instant specification wherein OSAS is distinguished from primary snoring by the degree of upper airway obstruction. The instant specification defines OSA as a condition of total functional collapse of the upper airway whereas snoring is a symptom of partial nocturnal upper airway obstruction.

However, the examiner argues that Barth et al. disclose treating partial upper airway obstruction (obstructive hypopnea) by administering a therapeutically effective amount of at least one proton pump inhibitor, such as lansoprazole. Therefore, Applicants have not distinguished the instant claims (i.e. treating partial nocturnal upper airway obstruction) from the teaching of Barth et al. (i.e. treating partial obstruction of the patient's airway).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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